STATE OF WEST VIRGINIA
DEPARTMENT OF HEALTH AND HUMAN RESOURCES

Bob Wise
Governor

Paul L. Nusbaum
Secretary

West Virginia Department of Health and Human Resources
Bureau for Medical Services
Pharmaceutical and Therapeutics (P & T) Committee
January 11, 2006 – 3:00 p.m. – 5:00 p.m.
Charleston Civic Center
WV Room 105
Charleston, West Virginia

M I N U T E S

Members Present:
David Avery, M.D.
John D. Justice, M.D.
Steven R. Matulis, M.D.
Barbara Koster, MSN, RNC-ANP
Harriet Nottingham, R. Ph.
Michael Grome, PA-C
Teresa Dunsworth, PharmD
James Bartsch, R.Ph.
Kristy H. Lucas, PharmD

Contract Staff/Provider Synergies Present:
Steve Liles, PharmD (by telephone)

Other Contract Staff/State Staff Present:
Stephen Small, RDTP

Members Not Present
Kevin W. Yingling, R.Ph., M.D.

DHHR/BMS Staff Present
Nancy Atkins, Commissioner
Nora Antlake, Counsel
Peggy King, Pharmacy Director
Gail Goodnight, Rebate Coordinator
Vicki Cunningham, DUR Coordinator
Lynda Edwards, Secretary

Present:

Astellas Pharma US: Linda Eason
AstraZeneca: Tom Farrah
Boehringer Ingelheim: David Large
Forest: Wayne Miller
Genzyme: Chris Nichols
GlaxoSmithKline: Cindy Snyder

Government Relations Specialist: Thom Stevens
Johnson & Johnson: Robert Fronius, Jeff Evans
Lilly: Todd Bledsoe
Organon: Tim Stanley
Pfizer: Shawnee Lewis, Chuck Dent, Kent Hunter, Glenn Self, Amber Willis, Jeff Borman
Roche: Archie Shew
Sanofi-Aventis: Walter Gose
Santarus: Todd Hickman, Angela Clay
Schering: Rob Marsh, Feng Ho
Sepracor: Larry Green
Takeda: Jeffrey Sheetz
TAP: Stacey Poole, Judy Ricci

I. Call to Order

Dr. Steven Matulis, Chairperson, called the meeting to order at 3:15 p.m.

II. Housekeeping

Peggy King, R.Ph., Pharmacy Director, was recognized, and she advised the audience on how the meeting would be conducted.

III. Introductions

All parties seated at the table introduced themselves and gave a brief statement about their professional credentials and affiliations.

Mrs. King explained that there would be no therapeutic reviews at this meeting.

IV. Approval of Minutes of August 17, 2005 Meeting

Chairman Matulis asked for approval of the minutes from the last meeting. A motion was made and seconded, votes were taken and the motion carried to approve the minutes as submitted.

V. Reports

Mrs. King asked that the Committee review two reports produced by Provider Synergies. She said that these reports are received on a quarterly basis and that the Committee does not normally have time to review these due to of the numerous agenda items that the Committee must address at the regularly scheduled meetings. Steve Liles, PharmD, Provider Synergies, participating by telephone, stated that the first report demonstrates compliance with the Preferred Drug List (PDL). It enables Provider Synergies to compare

the percentage of utilization of drugs in each class, both preferred and non-preferred and to identify areas where there may be problems in moving market share.

He stated that West Virginia has been successful in achieving a very high rate of PDL compliance. He said that the report identifies those classes where the percentage of PDL drug utilization is less than 90 percent and the explanation for the lower percentage in each particular class. He stated that control in utilization would result in substantial savings for the State.

Dr. Liles explained that some of the higher utilization of non-referred drugs in some of the classes was due to the more recent shift of particular drugs to non-preferred status. He said it was too early to see a drop in the utilization of these drugs because of grandfathering in the previous quarter.

The Committee expressed their interest in this report and agreed that it was valuable feedback for their work. They requested that total amounts be added to the report.

Dr. Liles reiterated that West Virginia is outstanding in controlling their Preferred Drug List compared to other states.

Dr. Liles said that the second report, the Savings Report, is also prepared on a quarterly basis. He stated that there is a time lag in the report due to data that is required to be obtained from Unisys and CMS. The report reflected data from the third quarter 2005. The report separates savings due to rebates and savings achieved through market shifts. He said Provider Synergies has compared the current cost per prescription for each class to the baseline cost per prescription at the beginning of the program in 2002, and provides this on a quarterly basis. He said that we have completed three full years of the PDL supplemental rebate program. During the first year (fourth quarter of 2002 through the third quarter 2003), the State saved $24.8 million. In year two, which ran from the fourth quarter 2003 to the third quarter 2004, the State saved $45.6 million. In year three, the savings increased to $61.1 million. He said that the work that the Committee has done in reviewing the drug classes and the recommendations for the PDL have resulted in $130 million in savings for the State since it started three years ago.

A Committee member asked for an explanation of federal rebates. Dr. Liles stated that Medicaid can only reimburse for drugs for which the manufacturers have signed a rebate agreement with the federal government (CMS). Prior to the Supplemental Rebate Program there were already federal rebates in place and the manufacturers who want their drugs covered by Medicaid have to sign with CMS. These rebate amounts are set by statute, not negotiated. He explained that supplemental rebates are negotiated and the total amount of rebates can vary based on the federal versus supplemental rebates.
A question was asked about one therapeutic class that has a significant percentage of non-preferred drug utilization, and therefore had negative savings. Dr. Liles explained that a negative market shift savings means that before supplemental rebates are considered, the drugs on the PDL are more costly than the drugs at baseline. He explained the supplemental rebates that are offered by the manufacturer will offset the

shift to more expensive drugs. So the market shift savings is reflected without rebates. He said that if you look at the AWP of a drug, which really has little bearing on the actual cost of the drug, relating to expensive drugs and shift utilization to more expensive drugs without rebates, there would be negative market shift savings. Once you put the rebates into the class, this results in a net savings for the State. The Committee member said that a more expensive drug with a supplemental rebate helps in the long run. Dr. Liles agreed. He also explained that there are instances when a brand name drug with supplemental rebates is less expensive for the state than using the generic equivalent. This would be an example of the report reflecting a negative market shift savings but the net savings will be positive because of the high supplemental rebate.

The Committee again agreed that these reports were very useful.

VI. Conflicts of Interest

Mrs. King said that she wanted to discuss conflicts of interest with the Committee. She stated that the Bureau has received different contacts from people regarding some of the positions that the Committee members have held but she also stated that she did not know whether there was any validity to the information. She wanted the Committee to help the Bureau to decide what are acceptable or unacceptable activities for Committee members. She said that new members would be coming on board with the Committee and she wanted to have the quidelines established to remove any gray areas, if possible. She said that if members were to serve on a speaker's bureau, an advisory board, be a consultant for a company, or be on retainer or receive talking points to use at a meeting that were directly provided by the manufacturer for a particular product, that those kinds of activities could be perceived as conflicts of interest. She said that the Committee is to consider clinical evidence and price and the Bureau does not want any kind of bias to cloud discussions. She wanted to have the Committee's input so that there will be clear guidelines for the new members.

A Committee member stated that they serve on numerous boards and that any board he served on asked for a conflict of interest statement. He said that he thought it was necessary that people state information that could be considered a conflict. Regarding the issue at hand, there are two types of lectures and seminars given - CME lectures and promotional ones. He said that if you are on a speaker's bureau for one company and always speaking for one company, that information needs to be stated. He said that the advantage of being on speakers' bureaus is that it gives you a chance to learn more about specific drugs and to form better opinions. He said that if you are speaker on only one company, that is a conflict of interest. He stated that most all physicians are involved on boards and speakers' bureaus for someone. He said that does not constitute bias, but if someone has a conflict, then you need to provide that information.

It was stated that monetary gifts and honorariums gave the appearance of conflicts of interest or alignment with a specific manufacturer. It was stated that unrestricted grants are usually given to speakers speaking for companies.

Another member said that they had to sign a conflict of interest statement for another committee they serve on that discloses stock options, percentages and percentage of income from different companies. This formula was used to determine possible conflicts of interest in specific areas. It was stated that some of the schools receive funding from manufacturers and give lectures to help educate the staff. He said that if you take that away you will eliminate qualified people. It was asked if the honoraria went to the university or the individual. It was said that sometimes these staff are required to bring in grants and then their salaries are supplemented with these types of grants.

A Committee member stated that professionals in a position to critically evaluate are oftentimes targeted for committees like this, are perceived as leaders and are often targets of industry for speakers' bureau and educational sessions. She said that if you try to find someone who is not a target she is not sure that is someone you necessarily want making decisions.

Mrs. King said that in the conflicts of interest forms the Committee has completed, she has not seen anything relating to conflicts, but when someone calls and asks, "Did you know that?", it can put the Bureau in an uncomfortable position. A Committee member said that you should have to ask the member about the situation. It was stated that the Committee member should abstain from voting when there is a conflict.

Mrs. King stated that when the Committee reached the section of the Bylaws that this area would be revised.

VII. Meeting Schedule

Mrs. King stated that the Committee has typically had two meetings a year. She said that she met with Secretary Walker a few months ago to talk about how the Committee needs to move forward since it is past the initial three-year appointment period. She recommended that in order to keep continuity of the group, the Secretary suggested that membership appointments be staggered. The Secretary said that two meetings a year does not give everyone enough time to get to know one another and to establish a cohesive group. She recommended that the Committee have four meetings a year.

Mrs. King said that because West Virginia is part of a pooling group (TOP$), that includes four other states, the other states are not willing to conduct four meetings and they only want two meetings. Because the majority rules in those situations, there can only be drug reviews at two meetings. She stated that the Committee would have to have other agenda items to discuss that are worthy to pull the members from their jobs to meet at the other meetings. She said the only agenda items that she could determine would be to have reports presented and reviewed such as those that were discussed today, and have more open to the floor time to allow for increased public input. The meeting could be shorter - two to three hours. A member said that maybe the members could talk about the more controversial classes. Mrs. King said that although no decisions could be made regarding preferred or non-preferred status due to the negotiation process, the Committee could review clinical information, or have presentations that they would be

interested in hearing about. Ms. King said that the other states were asked if they would go to three meetings and they declined. She said that she hoped the Committee would think of other agenda items that could be added that they would be interested in.

Commissioner Nancy Atkins stated that if there were three meetings, that extra meeting could be used to look at reports and see what has been accomplished throughout the year.

It was asked if conference calls could be set up for the members that have to travel long distances. Mrs. King said that it could be done, according to the Bylaws.

VIII. Revision of Bylaws

Commissioner Atkins suggested reviewing the Bylaws.

Mrs. King stated that the "Name and Purpose of the Bylaws" section had not changed. She said that "Membership" description had been changed. Commissioner Atkins explained that everyone's three-year term has expired and there was no process to prevent a turnover of the whole Committee. She stated that membership size would be increased from seven members to fifteen members. The Secretary would replace five members per year, so therefore, there would be no total turnover of the Committee every three years. Mrs. King stated that the Bureau had asked for another psychiatrist, pediatric specialist, infectious disease specialist, replacements for Dr. Gilligan, an osteopathic physician, and Dr. Yingling, an internal medicine University physician. It was stated that a primary care physician would be good. It was stated that Dr. Gilligan, and Dr. Yingling were primary care physicians. An endocrinologist was suggested. Mrs. King replied that the Bureau has asked the State Medical Association for three candidates in each of those categories. Dr. Avery suggested that there be another family practice representative.

Mrs. King said that in the "Terms of Membership", there was specific language for the 2006 appointments that would start a phase-in process. Commissioner Atkins read the revised section of Terms of Membership. Mrs. King said five members would be reappointed or replaced annually. The Commissioner explained that resignations would be handled with replacements with that specialty, if possible. This would insure the mixed composition of specialties of the members. It was asked if the specialties should be put in the Bylaws. It was decided that there was no need to be more specific.

Mrs. King said that there would be a drawing for the one- and two-year appointments. She stated that all of the new appointees would serve the three-year term. She explained that Mr. Grome would serve two more years because he was a new appointment and had only served one year.

Commissioner Atkins stated that the next section to review was "Conflicts of Interest". Mrs. King read the section to the members. It was decided that the Bureau would adopt a different disclosure form. It was stated that if there was a conflict of interest, that the

member should remove themselves from the discussion. A lengthy discussion ensued about conflicts of interest and compensation. It was decided that there would be a threshold put on the amount of compensation members could receive. This would be accomplished by filling out a conflict of interest disclosure form. Dr. Dunsworth offered to share a form that is used by a committee on which she serves and would provide this to Mrs. King before the next meeting. Commissioner Atkins asked Ms. Antlake if the Bylaws should include that disclosure statements would be completed annually. Ms. Antlake agreed.

Mrs. King read the "Confidentiality" section. She said that this was voted into the Bylaws from a previous meeting. She stated that all materials received from Provider Synergies were to be considered confidential materials and were for the members only.

The next section was "Resignations" and there were no changes to this section. The next section was "Removal" and it was changed from three to two consecutive absences constitute grounds for removal. She stated no changes were made to "Chairperson/Vice-Chairperson" section. The "Term of Office" section was changed to one year for terms. "Duties of Officers and Resignation of an Officer" had no changes. Meetings had changed to three meetings a year. It was asked if our meetings had to be the same as the other states, and Mrs. King stated that the two class review meetings had to be consistent with the other states. She said that now there would be a public comment period at all three meetings.

It was stated that members could call in but they are limited, and this cannot be done two consecutive times. Legal counsel was asked if members could also call in for Executive Session and this was approved. In the "Quorum" section it was changed to two consecutive meetings by telephone conferencing would constitute grounds for removal.

In the "Public Comments" section, Mrs. King stated that the comment period would be changed to 60 minutes and each person had a three-minute limit for comment. All handouts from the audience could be given to the Pharmacy Secretary for distribution to Committee members at the Executive Session. It was also explained that manufacturers could also send materials to be put in the Committee members' packets, but would be limited to two pages.

Commissioner Atkins read the section on Amendments of Bylaws. A motion was made to accept the Bylaws as amended. Motion was seconded, votes were taken and motion passed.

The drawing for one and two year terms of the Committee members was completed. The members and the terms they drew are as follows:

Two-year term: Dr. Matulis, Dr. Avery, Ms. Nottingham, Dr. Lucas, (and Mr. Grome from his previous appointment – see discussion above).
One-year term: Dr. Dunsworth, Ms. Koster, Mr. Bartsch, Dr. Justice, Dr. Yingling

Mrs. King stated that Dr. Gilligan had sent her his resignation, but that there is no official letter of resignation at this time for Dr. Yingling. Therefore, his position would be replaced for the one-year term. (See revised Bylaws on Bureau for Medical Services website at http://www.wvdhhr.org/bms/sPharmacy/PDL/bms_PDL_main.asp)

IX. Next Meeting Date

The next meeting date of the P & T Committee will be **February 8, 2005** at the Charleston Civic Center at 9:00 a.m.

X. Other Business

It was asked if the audience had any comments. It was asked about Speaker Sign Up. It was stated that there were no changes made to the Speaker Sign Up process. The Open Meetings Law would be followed. Commissioner Atkins stated that if anyone in the audience wanted, they could send recommendations to the Bureau.

Someone asked what the positions for reappointment would be and Mrs. King reiterated the positions mentioned earlier. Commissioner Atkins replied that the Committee will be comprised of four pharmacists, one nurse practitioner, one physician's assistant, and nine physicians.

A motion was made, was seconded, votes were taken and the motion carried to adjourn the meeting of the Pharmaceutical and Therapeutics Committee.